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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,613	11/28/2000	I. Lawrence Greenfield	7414.0022	7659

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EXAMINER
RILEY, JEZIA

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,613	GREENFIELD, I. LAWRENCE	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-87* is/are pending in the application.

4a) Of the above claim(s) *26-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Remarks

1. Applicants' arguments and amendments, filed on 8/30/02, have been approved and entered. They have been fully considered and they are deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 7-11, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Macfarlane (5,010,183).

Macfarlane discloses method for purifying DNA and RNA from a variety of sources, including cells, cell lysates, viruses, tissues, blood and other body fluids employing a cationic detergent to complex with the nucleic acids.

Preferred cationic detergents for use in the method are quaternary amine detergents. The nucleic acid yield may be further increased by the addition to the mixture of hydrolytic enzymes, such as proteinase K.

In one aspect the method for purifying DNA or RNA from a mixture of biological materials, comprises the step of adding a cationic detergent to a mixture containing the RNA or DNA in an amount sufficient to dissolve cells, solubilize any contaminating proteins and lipids in the mixture, and form insoluble hydrophobic complex between the nucleic acid and the detergent. The complex which comprises the RNA or DNA with the detergent is separated from the solubilized contaminants, and may be dissolved or dispersed in a polar organic solvent. Thereafter the DNA or RNA is recovered by the addition of a salt, which promotes the dissociation of the complex. Although many solvents are suitable for this purpose, presently preferred solvents for use in this step of the method include ethanol, methanol and formamide and mixtures thereof. The dissociation steps takes approximately 5-120 minutes, with gentle stirring or agitation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macfarlane (5,010,183) in view of Macfarlane (5,728,822).

Macfarlane (183) discloses method for purifying DNA and RNA from a variety of sources, including cells, cell lysates, viruses, tissues, blood and other body fluids employing a cationic detergent to complex with the nucleic acids.

Preferred cationic detergents for use in the method are quaternary amine detergents. The nucleic acid yield may be further increased by the addition to the mixture of hydrolytic enzymes, such as proteinase K.

In one aspect the method for purifying DNA or RNA from a mixture of biological materials, comprises the step of adding a cationic detergent to a mixture containing the RNA or DNA in an amount sufficient to dissolve cells, solubilize any contaminating proteins and lipids in the mixture, and form insoluble hydrophobic complex between the nucleic acid and the detergent. The complex which comprises the RNA or DNA with the detergent is separated from the solubilized contaminants, and may be dissolved or dispersed in a polar organic solvent. Thereafter the DNA or RNA is recovered by the addition of a salt, which promotes the dissociation of the complex. Many salts are capable of use in this dissociation step which is viewed to be inclusive of CaCl2. Although many solvents are suitable for this purpose, presently preferred solvents for use in this step of the method include ethanol, methanol and formamide and mixtures thereof. The dissociation steps takes approximately 5-120 minutes, with gentle stirring or agitation.

Macfarlane (822) discloses method for isolating RNA from a biological sample, including blood, involving the use of an aqueous, cationic surfactant solution comprising a selected quaternary amine. The selected quaternary amine is produced through the reaction of a quaternary amine hydroxide and an acid of the group consisting of phosphoric, sulfuric, formic, acetic, propionic, oxalic, malonic, succinic and citric. Preferably, the quaternary amine is either an alkyltrimethylammonium or an alkylbenzyldimethylammonium, where the alkyl group contains 12, 14, 16 or 18 carbons. One or more of the described surfactant solutions may be readily prepared in a kit for isolating ribonucleic acid from a biological sample. A presently preferred surfactant for such use is alkyltrimethylammonium oxalate, with 14 carbons in the alkyl group. Additional components of such a kit would include the reagents and containers necessary for the performance of the separating and dissociating steps of this method, i.e., the formamide solvent, the guanidinium isothiocyante solution, the lithium chloride solution and/or ethanolic solution. Optionally the reagents for accomplishing the additional purification steps identified above may also be included in such a kit for ready performance of this method. Other conventional components of kits for such isolation methods may also be included in a kit. EXAMPLE 8 describes RNA isolation using cationic surfactant and aurin tricarboxylic acid. An experiment similar to Example 7 was performed using 0, 0.5 or 5 mM aurin tricarboxylic acid in place of dithiothreitol. The best yield of undegraded RNA was obtained when 5 mM aurin tricarboxylic acid was added to the formamide extracting buffer. Aurin tricarboxylic acid is known to inhibit RNase.

Therefore it would have been obvious at the time the invention was made to one of ordinary skill in art to use the surfactants as disclose in Macfarlane (822) the motivation is that the surfactant solution is not excessively viscous, i.e., less than 2 cp. The surfactant solution does not crystallize under typical storage conditions, i.e., temperatures of about 0 to 30 C. and storage times of about one month. Further, when the surfactant is added to blood in the process of RNA isolation described below, and the mixture is centrifuged, the resulting pellet is of small volume relative to the volume of the blood used in the method, and not dark in color. Additionally, the pellet contains a substantial proportion, that is, greater than about 30%, of RNA endogenously present in blood or added to the surfactant simultaneously with the blood. The pellet does not contain substances, such as hemoglobin or its derivatives, in amounts which, after recovery of the RNA as described below, tend to inhibit the action of the reverse transcriptase, DNA polymerase, or other enzymes used in the detection of RNA.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

October 18, 2002

JEZIA RILEY
PRIMARY EXAMINER